REMARKS

This Amendment is responsive to the Office Action dated February 27, 2004. Applicant has amended claims 1, 4 and 6-8, and added new claims 9-17. Claims 1-17 are pending upon entry of this amendment.

Drawing Objection Under 37 C.F.R. § 1.83

As a preliminary matter, the Examiner objected to the drawings under 37 C.F.R. § 1.83(a) "because they fail to clearly show the exact structure of the shield and attachment detail." The Examiner further stated that, in particular, the shield has a higher elevation than the attachment detail in all of the cross-sectional drawings, but appears to have the same height in the adjacent drawings. With this Amendment, Applicant has submitted corrections to FIGS. 2a, 3a, 4a, 5a, and 6a, which should overcome the Examiner's objection.

Claim Rejection Under 35 U.S.C. § 102

In order to support an anticipation rejection under 35 U.S.C. § 102(b), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule of law is commonly referred to as the "all-elements rule."[1] If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. § 102(b) is improper. [2]

Woloszko and Lee, cited by the Examiner, fail to disclose several limitations set forth in original claims 1-6. For at least these reasons, Woloszko and Lee fail to establish a prima facie case of anticipation of Applicant's claims 1-6 under 35 U.S.C. § 102(b). Moreover, Woloszko and Lee fail to anticipate additional features set forth in claims 1-6, as amended. Therefore, Applicants respectfully traverse the rejections under § 102(b), particularly to the extent the Examiner may consider them applicable to the amended claims.

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[1] *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").
[2] *Id. See also Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

Woloszko et al.

In the Office Action, the Examiner rejected claims 1 and 3-6 under 35 U.S.C. § 102(b) as being anticipated by Woloszko et al. (US 5,938,596). With respect to claims 1 and 3-6, the Examiner stated that Woloszko discloses a medical lead for a neural stimulator. The Examiner further stated that, as illustrated in FIG. 2B, of Woloszko teaches a medical lead (6) having a connector (5) and electrode (7). The Examiner also referred to FIG. 4A of Woloszko and stated that the disclosed medical lead includes attachment details (15, 16, 17) arranged as recited in claims 1 and 3-6.

Claims 1 and 3-5

Woloszko fails to teach or suggest a implantable neurological stimulation lead comprising a lead body, a ring electrode carried on a distal end of the lead body, and a lead carrier having an attachment detail for coupling to the distal end and an electrode shield positioned by the attachment detail to insulate a portion of the ring electrode, as recited by Applicant's amended claim 1.

Woloszko makes no mention of an electrode shield positioned by an attachment detail to insulate a portion of a ring electrode, as recited in Applicant's claim 1. Moreover, Woloszko does not describe a ring electrode. Woloszko refers instead to a medical electrical lead that comprises a lead body and a semi-cylindrical "cuff" that positions electrode "tabs" within the cuff about a nerve.

It appears that the Examiner has equated the semi-cylindrical cuff (15), the inner long flap (16), and the outer short flap (17) of Woloszko to an attachment detail, as claimed. However, these three components in Woloszko do not couple to a lead distal end and position an electrode shield, as set forth in claim 1. Rather, the components from part of an electrode portion 7 that serves to mount the medical lead to a nerve. For example, Woloszko states:

> electrode portion 7 is constructed from three elements. Semi-cylindrical cuff 15, which has an inner long flap 16 mounted to root portion 18 of cuff so as to extend about the opening of the semi-cylindrical cuff ... enveloping the outer end portion of the long flap, is an outer short flap 17, which permits the cuff to stay mounted around the nerve and not be dislodged through the swelling of the nerve. Positioned within the interior surface of the semi-cylindrical cuff are three tab electrodes.[3]

[3] Woloszko, Col. 3, ll. 26-38

Woloszko does not even describe an electrode shield to insulate a ring electrode, as claimed, let alone an attachment detail to position such an electrode shield relative to the ring electrode. Instead, as mentioned above, Woloszko contemplates the use of electrode tabs within a semi-cylindrical cuff formed from flaps 16, 17.

Moreover, Woloszko does not teach or suggest an attachment detail selected from a group consisting of a clip, a ring, and a sleeve, as recited by Applicant's claim 3. Nor does Woloszko describe the use of more than one attachment detail, as recited by claim 4.

Claim 6

Woloszko also fails to disclose or suggest an implantable neurological stimulation lead comprising a first lead body with a ring electrode carried at a distal end of the first lead body, and means for coupling to the lead distal end and positioning an electrode shield to insulate a portion of the ring electrode, as recited by Applicant's amended claim 6.

As discussed above, Woloszko makes no mention of a ring electrode, nor the positioning of an electrode shield to insulate a portion of a ring electrode, as recited in Applicant's claim 6. Woloszko refers instead to a medical electrical lead that comprises a lead body and a semi-cylindrical cuff that positions electrodes within the cuff about a nerve. Again, the cuff described by Woloszko is used to mount to the nerve, rather than position an electrode shield relative to a ring electrode, as required by claim 6.

In summary, Woloszko does not disclose or suggest each and every feature of Applicant's amended claim 1 or Applicant's amended claim 6. Therefore, Applicant respectfully requests withdrawal of the rejection. In addition, claims 3-5 depend from independent claim 1. For at least the reasons discussed above with respect to claim 1, claims 3-5 are also in condition for allowance.

Lee et al.

The Examiner also rejected claims 1-6 under 35 U.S.C. § 102(b) as being anticipated by Lee et al. (US 5,265,608). In support of the rejection, the Examiner referred to FIG. 2 of Lee and

stated that Lee discloses a lead carrier having two attachment details (12, 13) and a shield (14, 15, and 16).

Claims 1-5

Lee makes no mention of a lead carrier having an attachment detail for coupling to the lead distal end and an electrode shield positioned by the attachment detail to insulate a portion of an electrode, as recited in Applicant's claim 1. Moreover, Lee fails to disclose such a shield in combination with a ring electrode, as set forth in amended claim 1. Lee refers instead to a neurological lead including an electrode assembly wrapped around a nerve to position an electrode at a desired location and deliver an anti-inflammatory drug to the nerve tissue. Hence, Lee describes a cuff-like arrangement somewhat similar to the cuff taught by Woloszko.

It appears that the Examiner equated metallic foils (12, 13) from FIG. 2 of Lee to an attachment detail, as set forth in Applicant's claims. The metallic foils (12, 13) do not from an attachment detail for coupling to a lead distal end and positioning an electrode shield to insulate an electrode. In fact, the metallic foils (12, 13), themselves, are electrodes in the lead described by Lee. According to Lee, the metallic foils are disposed within a polymeric matrix layer (16) which is attached to an outer substrate (15) that includes a molded portion (14). Lee states:

> The metallic electrode elements are positioned on the polymeric matrix layer opposite the outer substrate...The metallic electrode elements contact the nerve tissue directly and are electrically coupled to an insulated lead which couples to remote electronic circuitry.[4]

Applicant respectfully submits that the metallic foils described by Lee cannot function as both the electrodes and the attachment detail that positions an electrode shield to insulate the electrodes.

Lee describes the outer substrate (15) as being used to mount the metallic foils (12, 13) adjacent a nerve. Lee states "the outer substrate is wrapped about the nerve at the desired location, and the edges of the outer substrate are sutured to hold the electrode in place."[5] Furthermore, the polymeric matrix layer (16) also does not form an electrode shield. According to Lee, the polymeric matrix layer (16) is embedded with an anti-inflammatory drug, which is

[4] Lee, Col. 2, ll. 11-19.
[5] Lee, Col. 2, ll. 13-16.

permitted to leach out at a desired rate to treat the inflammation and irritation of the nerve tissue caused by contact with the electrode.

Moreover, Lee does not teach or suggest a second lead body configured for coupling to the attachment detail of the lead carrier to space the second lead body in relation to the first lead body, as recited by Applicant's claim 2. Lee also does not teach or suggest an attachment detail selected from a group consisting of a clip, a ring, and a sleeve, as recited by Applicant's claim 3. Nor does Lee suggestion the incorporation of more than one attachment detail, as recited by claim 4.

Claim 6

Lee fails to disclose or suggest an implantable neurological stimulation lead comprising a first lead body with a ring electrode carried at a distal end of the first lead body, and means for coupling to the lead distal end and positioning an electrode shield to insulate a portion of the ring electrode, as recited by Applicant's amended claim 6.

As discussed above, Lee refers instead to a neurological lead including an electrode assembly wrapped around a nerve to position an electrode at a desired location and deliver an anti-inflammatory drug to the nerve tissue. The metallic foils (12, 13) do not comprise a means for coupling to a lead distal end and positioning an electrode shield to insulate an electrode. In fact, the metallic foils (12, 13) are, themselves, electrodes disposed within a polymeric matrix layer (16) which is attached to an outer substrate (15).

In summary, Lee does not disclose or suggest each and every feature of Applicant's amended claim 1 or Applicant's amended claim 6. Therefore, Applicant respectfully requests withdrawal of the rejection. In addition, claims 2-5 depend from independent claim 1. For at least the reasons discussed above with respect to claim 1, claims 2-5 are also in condition for allowance.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 7 and 8 under 35 U.S.C. § 103(a) as being unpatentable over Lee et al. (US 5,265,608). Applicant respectfully traverses the rejection to the extent such rejections may be considered applicable to the claims as amended. Lee et al.

fails to disclose or suggest the invention defined by Applicant's claims, and provides no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

It is well established that the Examiner bears the burden of establishing a prima facie case of obviousness.[6] In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention.[7] A prima facie case of obviousness is established only when this burden is met.

Lee lacks any teaching that would have suggested a method for attaching a lead carrier to a neurological stimulation lead, comprising aligning a first lead body in the lead carrier, inserting the first lead body in an attachment detail of the lead carrier, positioning a first ring electrode on the first lead body in relation to an electrode shield positioned by the attachment detail, aligning a second lead body in the lead carrier, inserting the second lead body in the attachment detail of the lead carrier, and positioning a second ring electrode on the second lead body in relation to the electrode shield, as recited by Applicant's amended claim 7.

In support of the rejection, the Examiner asserted, without citing any other prior art reference, that it is considered obvious to one of ordinary skill in the art to "attach the lead carrier by aligning, inserting and positioning given the clip design disclosed by Lee." Applicant respectfully disagrees with the Examiner's conclusion of obviousness.

As discussed above, it appears that the Examiner has equated the metallic foils (12, 13) with an attachment detail (27), as set forth in claim 7. However, Lee describes the metallic foils (12, 13) as metallic electrode elements that contact the nerve tissue directly and are electrically coupled to an insulated lead which couples to remote electronic circuitry. Therefore, one of ordinary skill in the art would have found no teaching in Lee that would have suggested positioning ring electrodes in relation to an electrode shield positioned by an attachment detail.

Moreover, in FIG. 2, extensions (10, 11) form conductor coils, which are electrically coupled to metallic foils (13, 12), respectively. Extensions are mounted within a lead body formed by an outer insulating sheath (9). Accordingly, extensions (10, 11) do not form first and second lead bodies, as required by claim 7. Instead, extensions (10, 11) are merely separate

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[6] *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).
[7] *In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995).

electrical conductors within a single lead body (9). In view of this difference, Lee contains no teaching that would have guided one of ordinary skill in the art to align and insert first and second lead bodies, as defined by claim 7.

Claim 8 depends from independent claim 7 and is therefore also in condition for allowance.

For at least the reasons discussed above, the Examiner has failed to establish a prima facie case of obviousness of Applicant's claims 7 and 8 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

New Claims

In this Amendment, Applicant has added new claims 9-17.

Claims 9-11 defines an implantable neurological stimulation lead comprising a lead body, a ring electrode disposed at a distal end of the lead body, an electrical connector disposed at a proximate end of the lead body, a conductor electrically connecting the ring electrode to the electrical connector, an electrically insulative shield sized to extend over a portion of the ring electrode; and an attachment mechanism to attach the shield to the lead body. According to claims 9-11, the shield at least partially insulates the portion of the ring electrode from tissue at an implantation site on a side of the shield opposite the ring electrode.

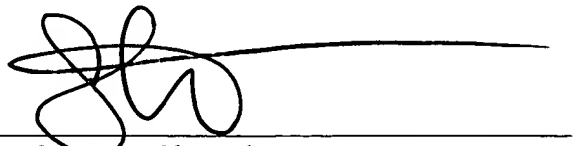
Claims 12-17 define an implantable neurological stimulation lead assembly comprising a first lead body having a first ring electrode at a distal end of the first lead body, a second lead body having a second ring electrode at a distal end of the second lead body, an electrically insulative shield sized to extend over portions of the first and second ring electrode, and an attachment mechanism to attach the shield to the first and second lead bodies. The shield set forth in claim 12 at least partially insulates the portions of the first and second ring electrodes from body tissue at an implantation site on a side of the shield opposite the first and second ring electrodes.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any

additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 5-26-04

By: 

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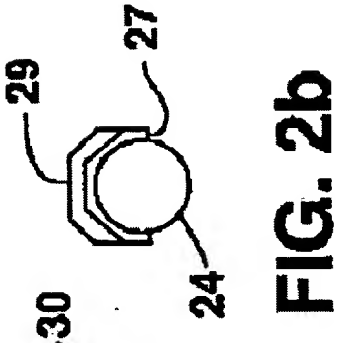

FIG. 2b

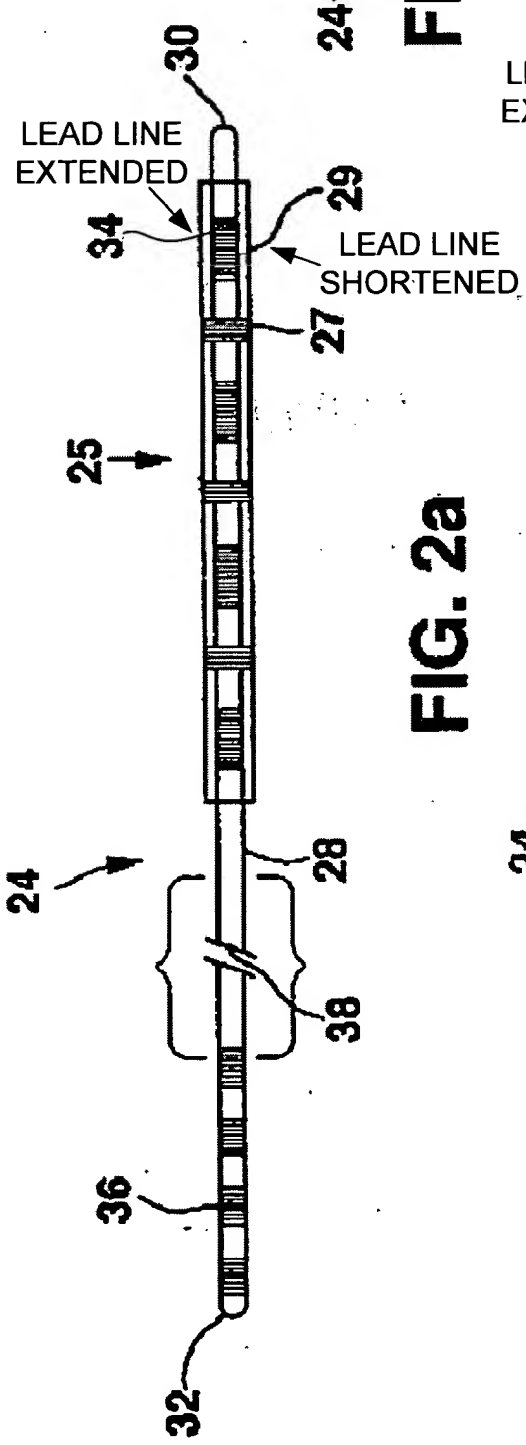

FIG. 2a

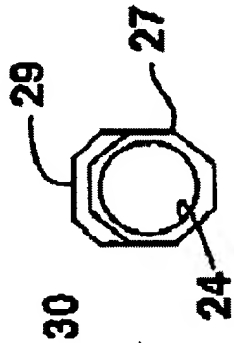

FIG. 3b

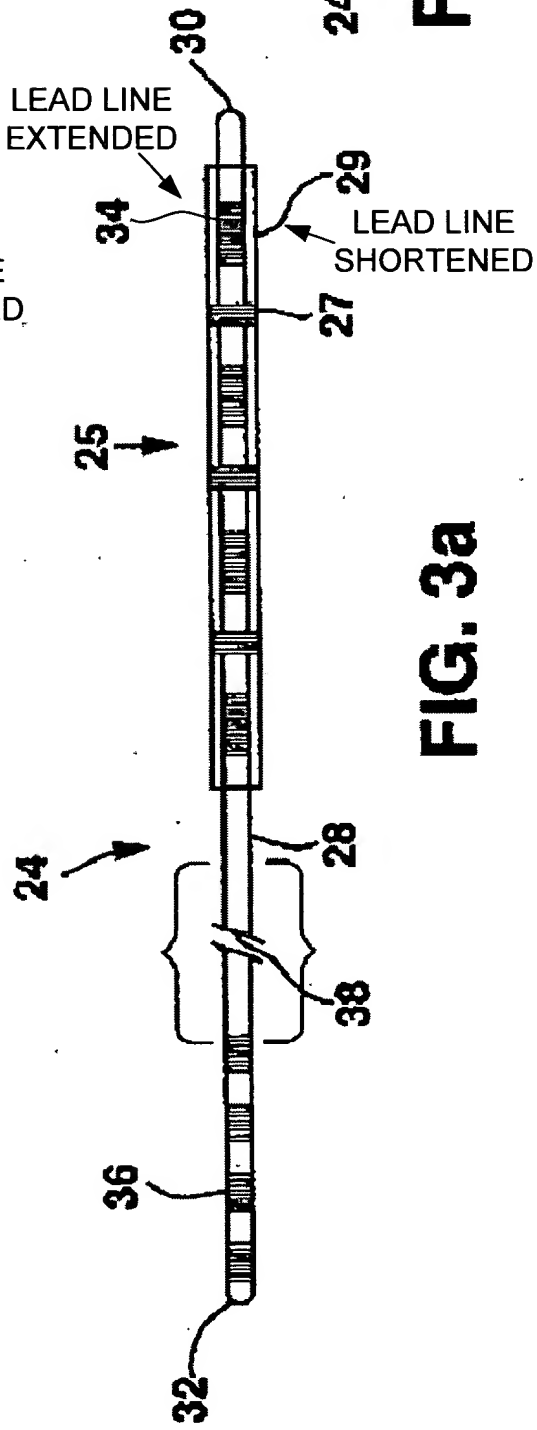

FIG. 3a

Annotated Sheet Showing Changes
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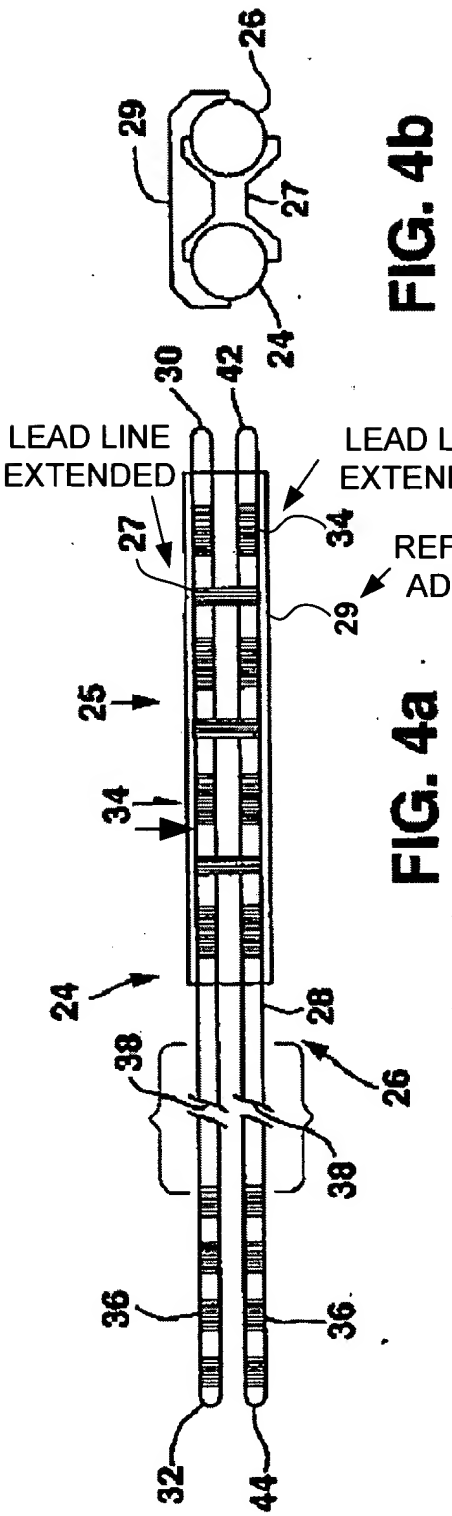

FIG. 4b

FIG. 4a

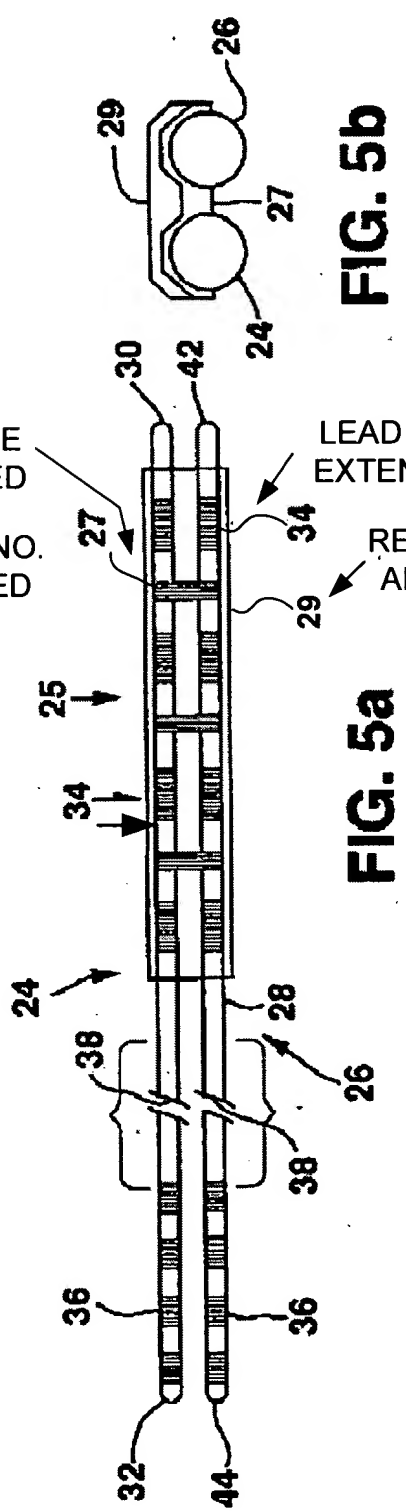

FIG. 5b

FIG. 5a

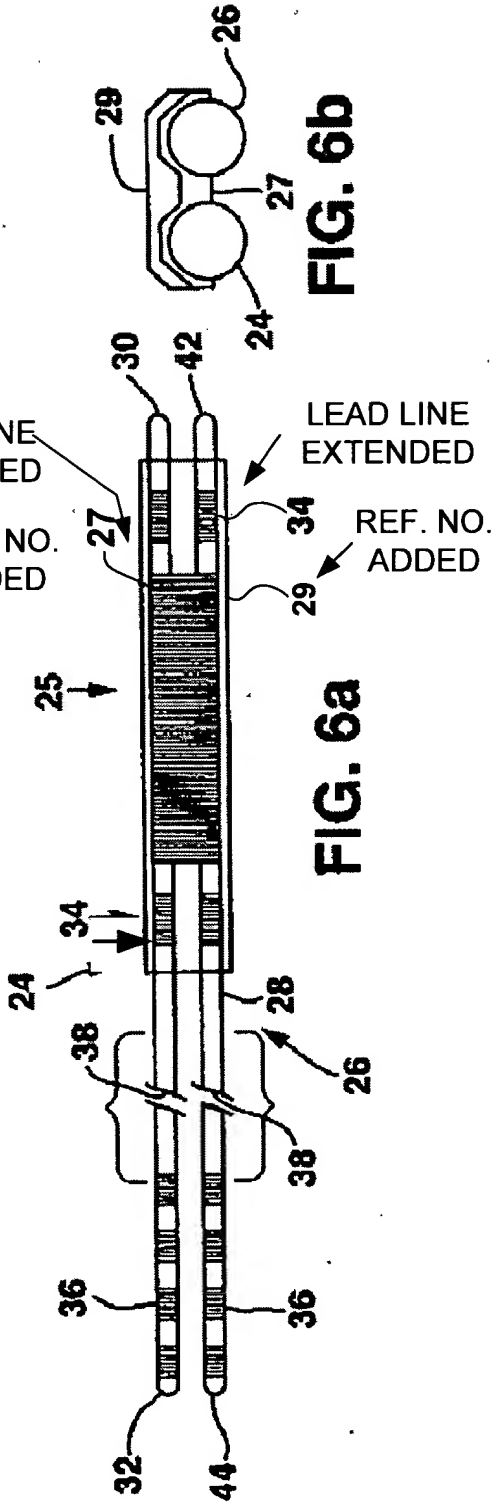

FIG. 6b

FIG. 6a